

Applicant : Miller  
Appl. No. : 10/595605  
Examiner : Roland Dinga  
Docket No. : 13634.4013

### Amendments to the Claims

Please cancel claims 1-17, 19, 20, 35, 44-49 and 56-62 without prejudice.

This listing of claims will replace all prior versions and listings of claims in the application:

1-17. (cancelled):

18. (currently amended): The ~~device~~ balloon as claimed in claim ~~42~~ 45, wherein the heart assist device is configured for extra-aortic counter-pulsation and the balloon is positioned on the exterior of an arterial vessel.

19-20. (cancelled)

21. (currently amended): The ~~device~~ balloon as claimed in claim ~~42~~ 45, wherein, when the balloon is inflated, the flexure region has a radius of curvature of at least 0.1 mm.

22. (currently amended): The ~~device~~ balloon as claimed in claim 21 wherein, when the balloon is inflated, the flexure region has a radius of curvature of approximately 1.0 mm.

23. (currently amended): The ~~device~~ balloon as claimed in claim 22, wherein, when the balloon is inflated, the flexure region has a radius of curvature of approximately 3.0 mm.

24. (currently amended): The ~~device~~ balloon as claimed in claim ~~42~~ 45, wherein the ratio of the diameter of the balloon neck portion to the balloon flexure region is no more than approximately 4: 1.

25. (currently amended): The ~~device~~ balloon as claimed in claim ~~42~~ 45, wherein the ratio of the diameter of the balloon neck portion to the balloon flexure region is approximately 3: 1.

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26. (currently amended): The ~~device~~ balloon as claimed in claim 42 ~~45~~, wherein the ratio of the diameter of the balloon neck portion to the balloon flexure region is approximately 2: 1.

27. (currently amended): The ~~device~~ balloon as claimed in claim 42 ~~45~~, wherein the bushing has an inlet/outlet bore.

28. (currently amended): The ~~device~~ balloon as claimed in claim 27, wherein the bore also includes one or more internal restrictions adapted to prevent suction of the balloon into the bore.

29. (currently amended): The ~~device~~ balloon as claimed in claim 42 ~~45~~, wherein the balloon is formed from silicone, polyurethane or a polyurethane-polysiloxane block co- polymer.

30. (currently amended): The ~~device~~ balloon as claimed in claim 42 ~~45~~, wherein the balloon is formed by mandrel dipping.

31. (currently amended): The ~~device~~ balloon as claimed in claim 42 ~~45~~, wherein the balloon is formed by dipping a suitably shaped mandrel into the polymer and allowing a thin coating of the polymer to cure on the mandrel.

32. (currently amended): The ~~device~~ balloon as claimed in claim 31, wherein the balloon is made of 2 to 4 coatings of the polymer.

33. (currently amended): The ~~device~~ balloon as claimed in claim 32, wherein the balloon a total thickness of 150-300 microns.

34. (currently amended): The ~~device~~ balloon as claimed in claim 42 ~~45~~, wherein the balloon neck portion is a snug sealing fit over the bushing exterior.

35. (cancelled)

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36. (currently amended): The ~~device~~ balloon as claimed in claim ~~50~~ 35, wherein the bushing has a slightly tapered neck portion adapted for engagement with the balloon neck portion.

37. (currently amended): The ~~device~~ balloon as claimed in claim 36, wherein the bushing neck portion has a converging taper in the direction of the balloon.

38. (currently amended): The ~~device~~ balloon as claimed in claim ~~42~~ 45, wherein the balloon is held in place on the aorta by a flexible wrap which extends about the aorta and bears against the first body portion of the balloon or a shroud mounted thereon.

39. (currently amended): The ~~device~~ balloon as claimed in claim 38, wherein the flexible wrap is shaped to fit the second body portion of the balloon.

40. (currently amended): The ~~device~~ balloon as claimed in claim 39, wherein the flexible wrap is also shaped to fit the neck portion.

41. (currently amended): The ~~device~~ balloon as claimed in claim 38, wherein the flexible wrap is inelastic or slightly elastic so that its stretch and flexibility characteristics substantially match those of the native aorta.

42. (currently amended): A flexible inflatable balloon for a blood displacing heart assist device, the balloon including:

a tubular neck portion having first and second ends and being adapted for connection at its first end to an inflation line;

an integrally formed balloon body, the body including:

a substantially annular first body portion connected at its inner periphery to the ~~neck portion~~ second end of the neck portion; and

a substantially oval or circular second body portion ~~connected at its outer periphery to the outer periphery of the first body portion, and~~

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~~the outer peripheries of the first and second body portions are connected along an annular inwardly concavely curved flexure portion formed integrally with the outer peripheries of the first and second body portions, wherein the flexure portion is adapted to maintain a radius of curvature on its inner surface during deflation of the balloon when an inside surface of the second body portion is drawn into contact with at least a portion of an inside surface of the first body portion, and a convex shape during inflation of the balloon movement of the second body portion between inwardly concave and outwardly concave during deflation and inflation of the balloon respectively.~~

43. (currently amended): The balloon as claimed in claim 42, wherein the balloon body and the neck portion are ~~is formed integrally as a single piece.~~

44-49. (cancelled)

50. (currently amended): The balloon as claimed in claim 42, and further including a bushing adapted for connecting the neck portion of the balloon with the inflation line ~~connection to a hydraulic or pneumatic power source.~~

51. (currently amended): The balloon as claimed in claim 50, wherein the bushing is formed with internal restrictions such as flutes, ribs, or secondary lumens to prevent the balloon from being sucked into the bushing during deflation of the balloon.

52. (previously presented): The balloon as claimed in claim 50, wherein the neck portion of the balloon is adapted for sealing connection with the bushing.

53. (currently amended): The balloon as claimed in claim 50, wherein the bushing has a taper adapting the relatively large diameter of the neck of the balloon to the relatively small diameter of the inflation line ~~a hydraulic or pneumatic fluid line connecting the balloon to a power source.~~

54. (original): The balloon as claimed in claim 53, wherein this taper is elongated to enhance the flexibility of the bushing along its central axis.

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55. (previously presented): The balloon as claimed in claim 42, wherein the balloon has in its longitudinal plane, a gentle arc of the order of radius of 150-300mm.

56-62. (cancelled)

63. (New) A flexible inflatable balloon for a blood displacing heart assist device, the balloon including:

a neck portion having first and second ends;

a substantially annular first body portion connected at its inner periphery to the neck portion second end; and

a substantially oval or circular second body portion connected at its outer periphery to the outer periphery of the first body portion, the outer peripheries of the first and second body portions are connected along an annular inwardly concavely curved flexure portion adapted to maintain a radius of curvature during movement of the second body portion between inwardly concave and outwardly concave during deflation and inflation of the balloon respectively, wherein the balloon has in its longitudinal plane, a gentle arc of the order of radius of 150-300 mm.